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# Real-Time Magnetic Resonance Imaging–Guided Transarterial Aortic Valve Implantation In Vivo Evaluation in Swine

Real-time magnetic resonance imaging (rtMRI) is considered attractive for guiding transarterial aortic valve implantation (TAVI). Compared with X-ray fluoroscopy, rtMRI offers unrestricted scan plane orientation and an unsurpassed soft-tissue contrast with simultaneous device visualization, potentially allowing enhanced positioning accuracy together with online monitoring of cardiac function and immediate detection of complications. Additionally, MRI offers noninvasive assessment of cardiovascular anatomy and function for preinterventional screening as well as immediate morphologic and functional assessment of the implanted prosthesis and may, thus, be envisioned as a single comprehensive imaging modality for TAVI.

We, therefore, sought to assess the preclinical feasibility of entirely rtMRI-guided TAVI in a swine model (female domestic pigs weighing 70.5 to 86.5 kg) using the original CoreValve (Medtronic, Minneapolis, Minnesota) prosthesis without alterations in conjunction with a modified, MRI-compatible delivery device (1).

rtMRI-guided transfemoral (n = 2) and transsubclavian (n = 6) TAVI was performed in a 1.5-T whole-body MRI scanner (Magnetom Avanto, Siemens Healthcare Sector, Erlangen, Germany). Conventional x-ray fluoroscopy and angiography were performed for comparison. After pre-interventional evaluation using standard steady-state free-precession imaging with electrocardiographic gating and time-resolved retrospective image reconstruction (cine-TrueFISP retro) (TR, 40 ms; TE, 1.1 ms; flip angle, 62°; FOV, 380 × 330 mm<sup>2</sup>; matrix, 192 × 168; slice thickness, 6 mm; bandwidth, 930 Hz/pixel; image acquisition time, 15 s for a single slice acquired over 20 phases of the cardiac R-R interval) and electrocardiography-triggered, flow-sensitive, phase-contrast sequences (TR, 62 ms; TE, 3.5 ms; flip angle, 30°; FOV, 320 × 220 mm<sup>2</sup>; matrix, 192 × 132; bandwidth, 555 Hz/pixel; acquisition time, 1 min 52 s; velocity encoding value, 100 cm/s), TAVI was performed using rtMRI fluoroscopy based on a commercially available interactive real-time projection reconstruction TrueFISP sequence with radial k-space filling during free breathing and without cardiac triggering that was modified to achieve a frame rate of 7 frames per second (TR, 3.0 ms; TE, 1.5 ms; flip angle, 70°; FOV, 360 × 360 mm<sup>2</sup>; matrix, 192 × 192; bandwidth, 1530 Hz/pixel; slice thickness, 6 mm). Images were displayed without delay inside the scanner room and could be adapted interactively according to the operator's (P.K.) needs while the sequence was running. After TAVI, real-time TrueFISP, cine-TrueFISP retro, and flow-sensitive phase-contrast sequences were used to verify procedural success. Autopsies were performed to validate MRI findings.

Three-point localizer sequences allowed for rapid detection (11 ± 3 min) of all scan planes required for preinterventional evaluation,

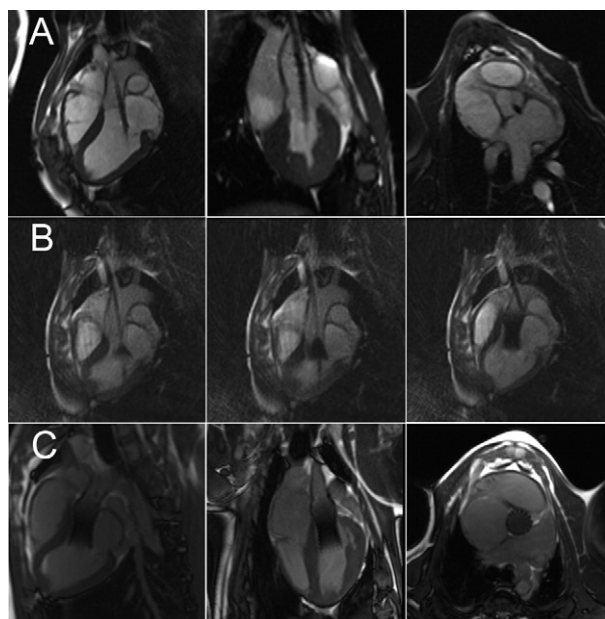
procedural guidance, and post-procedural validation. High-resolution TrueFISP retro sequences enabled detailed visualization of all procedurally relevant anatomic landmarks and allowed precise measurements (aortic annulus diameter in long axis, 17 ± 3 mm; aortic arch diameter, 21 ± 4 mm; distance from aortic annulus to left and right coronary ostium, 9 ± 3 and 10 ± 2 mm; access vessel diameter, 6.9 ± 1.2 mm) in good accordance with measurements on previous angiographic images (mean error, 0.4 ± 0.3 mm; p = NS) and during autopsy (mean error, 0.5 ± 0.2 mm; p = NS).

Passive device visualization using real-time TrueFISP sequences provided reliable imaging guidance during TAVI superior to fluoroscopy. Mild susceptibility artifacts confined to the loaded stent valve enabled adequate determination of the position of stent valve and delivery system in relation to the surrounding anatomy without undue image distortion, allowing a precise, real-time anatomic orientation during device navigation through the vasculature, aortic valve passage, positioning and deployment of the prosthesis, and catheter withdrawal.

In 6 of 8 animals, an oversized 26-mm CoreValve prosthesis was successfully placed across the aortic annulus without dislocation, coronary artery obstruction, or impairment of the mitral valve, as confirmed by autopsy (rtMRI acquisition time, 4 ± 2 min) (Fig. 1). However, 2 implant failures occurred. The first was a result of unsuccessful aortic arch passage due to insufficient support by the initially used MRI-compatible, soft polymer guidewire and led to a controlled deployment of the stent valve in the thoracic aorta, which is sometimes required in clinical application when the prosthesis dislocates into the ascending aorta during deployment. As a consequence, we continued our experiments without guidewire support and focused on the straighter transsubclavian access route. The second implant failure occurred due to perforation of the left ventricular apex caused by the delivery device, which was inadvertently pushed with too much force, this complication being immediately detected by rtMRI. Both cases indicate that rtMRI might improve both precision and safety of the TAVI procedure.

Postprocedural TrueFISP retro sequences allowed precise structural evaluation of the procedural result in good accordance with autopsy findings. Flow-sensitive, electrocardiography-triggered, phase-contrast sequences with imaging planes placed approximately 1 cm below and above the nitinol stent frame confirmed good systolic transvalvular blood flow without diastolic regurgitation.

The current study demonstrates the preclinical feasibility of entirely MRI-guided TAVI. As a single imaging modality, MRI offered comprehensive diagnostic evaluation of the relevant cardiac and vascular anatomy for adequate interventional planning, real-time procedural guidance with excellent anatomic orientation,



**Figure 1** Transsubclavian TAVI

After initial device position was confirmed in parasagittal and axial orientations using cine-TrueFISP retro sequences (A), the stent valve was deployed step-wise across the aortic annulus while monitoring with real-time TrueFISP imaging (B). After implantation, cine-TrueFISP retro sequences were repeated to confirm valve positioning (C).

immediate evaluation of procedure-related complications, and post-interventional validation of treatment success with a total procedure time of  $61 \pm 13$  min. Complementary to reduction of radiation exposure and nephrotoxic contrast media, rtMRI guidance, therefore, provides clinically relevant advantages over conventional X-ray-fluoroscopy and warrants further attention. These advantages should encourage future efforts to translate rtMRI-guided TAVI into clinical application using commercial but modified or entirely novel devices (2,3) and to overcome remaining obstacles such as the development of suitable, MRI-compatible guidewires.

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## Letters to the Editor

## Relationship Between Sprint Fidelis Leads and Patient Mortality

We read with interest the report of all-cause mortality in patients with Fidelis leads as compared with those with nonadvisory leads (1). Among 1,030 Fidelis patients (Minneapolis, Minnesota) and

1,641 Quattro patients (Minneapolis, Minnesota) over a mean follow-up period of 34.4 and 39.9 months, respectively, there was no difference in adjusted survival rates. The authors contend that their data support the current manufacturer's strategy of "continued clinical follow-up with the addition of the Lead Integrity Alert (LIA)" and conclude that this "argues against prophylactic removal of a normally functioning Fidelis lead" (1). In the accompanying editorial, Faddis (2) states that these data by Morrison et al. (1) "provide valuable guidance" with respect to lead management